REMARKS/ARGUMENTS

1. Claims 1-20 were previously pending. Claims 1-20 were rejected by Office Action dated August 26, 2003. Claims 3-12 and16-20 have been amended. Claim 21 has been added.

It is believed that this amendment places the application in condition for allowance and that therefore entry is appropriate.

2. Amended Claims:

Support for the claims as amended can be found in the specification as filed.
The amended claims, 3-12 and16-20 are set forth to claim a composition set forth in the application. No new matter has been introduced by amendment.

Applicants hereby request further examination and reconsideration of the application, in view of the amendments and remarks.

3. Added Claims:

Claim 21 has been added to this application. New Claim 21 is drawn to the elected invention. New Claim 21 recites a composition which has protectant and/or eradicant activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the

essential oil, preferably wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, preferably wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v). Support for new Claim 21 can be found in the specification as filed. Specifically, support for the new claim is found at least in the Example 2, Table 2; Example 3, Tables 4, 5, and 7; Example 4, Table 9; Example 5, Table 10.

In accordance with the Examiner's comments, new Claim 21 is set forth to claim a composition which has protectant and/or eradicant activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the essential oil, preferably wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, preferably wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v). as set forth in the application. No new matter has been introduced by amendment.

4.
- Claims 1, 2, 4, 5, 10-13 and 16-20 have been rejected under 35 U.S.C. 102(a).
- Claims 3, 6-9, 14 and 15 have been rejected under 35 U.S.C. 103(a).

Rejections of Claims under 35 U.S.C.102(a)

5. The Examiner has rejected Claims 1, 2, 4, 5, 10-13 and 16-20 under 35 U.S.C.

102(a), as "being anticipated by Atsumi *et al.* (JP 200217509) for the reasons given in the Office Action mailed 12/04/02, Paper No.6".

The Examiner states in Paper No. 6 that "Atsumi *et al.* discloses a freshness retaining composition that includes both the recited chitosan and the recited hinokitiol (an essential oil)", that "Atsumi *et al.* discloses the two antibacterial agents to be within the disclosed amounts, so that the composition of Atsumi *et al.* would inherently achieve any synergistic result that applicants' composition is capable of achieving", and that "Atsumi *et al.* also teaches bringing vegetables including cut vegetables into direct contact with the freshness retaining/antibacterial composition" (Page 2).

Applicant respectfully traverses the rejection. It is stated in the MPEP (MPEP 2131) that "[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" and that "[T]he identical invention must be shown in as complete detail as is contained in the ... claim."

Claims 1 and 2 have been canceled. This rejection is overcome since it is believed that new Claim 21, amended Claims 4, 5, 10-12, and 16-20 , and Claim 13 patentably distinguish from Atsumi *et al.* Atsumi *et al.* do not claim "chitosan *salts*". The instant specification discloses chitosan salts, chitosan-sorbate, chitosan-acetate, and chitosan-propionate, for example, in Example 2, Table 2; Example 3, Tables 4, 5, and 7; Example 4, Table 9; Example 5, Table 10. The claims recite "chitosan salts". Atsumi *et al.* claim chitosan. Atsumi *et al.* disclose that "when dissolving a lot of chitosan, it does not require using organic acids, such as required vinegar..." (Paragraph 13). Atsumi *et al.* further disclose that in order "to carry out this invention, a hinokitiol and chitosan are

first dissolved in the alcoholic tablet containing ethanol..." (Paragraph 14). The characteristics of the chitosan salts of the invention thus are different than the characteristics of chitosan of Atsumi *et al.* according to Atsumi *et al.*

6. The Examiner states that "[I]t is noted that the amendment urges that the synergistically effective amount is a 'critical' element, but, as noted above, this 'critical' amount is not disclosed, let alone claimed. ... Atsumi discloses the weight percent based on the carrier, not on the product so that the amount of hinokitiol and chitosan based on the total weight of the food product would be smaller than those numbers quoted by applicants" (Paper No. 8, Paragraph bridging pages 2 and 3).

In accordance with the Examiner's comments, new Claim 21 is set forth to claim synergistically effective amounts. Claim 21 recites "a composition which has protectant and/or eradicant activity and which substantially inhibits bacterial and fungal growth, comprising a chitosan salt and an essential oil in a synergistically effective amount wherein the chitosan salt is present in an amount which is not inhibitory in the absence of the essential oil, preferably wherein the concentration of the chitosan salt is in the range of 0.0016 - 0.1% (v/v), and wherein the essential oil is present in an amount which is not inhibitory in the absence of the chitosan salt, preferably wherein the concentration of the essential oil is in the range of 0.025 - 0.1% (v/v)".

Applicant disagrees with the Examiner's assertion that the amount of hinokitiol and chitosan of Atsumi *et al.* **would be smaller** than those numbers quoted by Applicant. Atsumi *et al.* disclose "hinokitiol in an amount of preferable 5.0-20 wt% (based on ethanol), chitosan in an amount of preferably 0.005-10 wt% (based on ethanol)". The ranges disclosed in the instant specification and recited in new Claim 21 is the range of

0.025 - 0.1% (v/v) for the essential oil and the range of 0.0016 - 0.1% (v/v) for the chitosan salt. Atsumi *et al.* disclose "in each example, % should be displayed in weight %" (Paragraph 17). The instant specification discloses and the instant claims recite amounts as per cent volume/volume. Based on the facts that the density of ethanol is 0.8 g/ml and the densities of common plant oils are found to be 0.91-0.93 g/ml (as shown on the website hypertextbook.com (see Appendix A), there would be only an approximately 10% difference between concentrations based on wgt/wgt and vol/vol. Applicant's range of concentrations differ from the range of concentrations of Atsumi *et al.* by more than 10%. Thus, the concentrations of essential oils and chitosan salts of Applicant are indeed smaller.

Applicant respectfully disagrees with the Examiner's statement regarding further "dilution". According to the Examiner's interpretation, the composition of Atsumi *et al.* is further "diluted" when in contact with the food product, thus resulting in lower concentrations than those of Applicant. According to such an interpretation, both Applicant and Atsumi *et al.*"dilute" the compositions when *treating* food products; whether it is lettuce (Atsumi *et al.*) or cut fruit (the instant invention), the compositions are "diluted "by the mass of the food product.

Atsumi *et al.* actually discloses "**diluting the freshness retaining agent** to 0.1-10 wt. %". Thus, a dilution of 10%, the greater dilution, would result in a concentration range of essential oil, for example, of 0.5-2 %, from an original concentration range of 5-20%. This is still far more concentrated than the 0.025 - 0.1% of the invention.

7. The instant specification discloses "[A]s used herein, the term "synergism" is intended to include both an increased spectrum of activity (*i.e.*, greater activity against a broad spectrum of microorganisms), and/or increased efficacy (*i.e.*, greater activity

against specific organisms than that predicted by use of either agent alone). The increased antimicrobial and antifungal activity of the synergistic combination permits the use of smaller amounts of each agent thereby decreasing costs and minimizing other problems, *e.g.*, toxicity, solubility, availability. Effectiveness against a broad spectrum of microorganisms broadens the utility of the synergistic product based on its effectiveness in environments containing many and diverse microorganisms which must be controlled" (Page 6). The composition of Atsumi *et al.* comprises concentrations of hinokitiol and chitosan that inhibit when used alone, although not very well. The combination of a somewhat inhibitory concentration of hinokitiol and a somewhat inhibitory concentration of chitosan results in somewhat better inhibition, which Atsumi *et al.* consider a synergistic effect (Paragraph 21). However, in the art, such results would be considered little more than additive. The composition of Applicant, however, comprises concentrations of essential oils and chitosan that absolutely do not inhibit by themselves, but inhibit totally or substantially when combined, *i.e.*, they act synergistically. Combining two substances in non-inhibitory concentrations, unexpectedly results in a synergistic response. See, for example, Tables 6 and 8, Pages 18 and 19.

8. The Examiner states that Applicant has "urged that Atsumi does not specifically mention that his composition is an antifungal agent; only that it is an antibacterial agent. Whether the composition is an antifungal agent or not is a property or capability of that composition. Atsumi discloses a composition that is to be added to produce and contains both of applicants constituents – chitosan and hinokitiol. ... Thus, in the absence of any proven criticality to the contrary, it appears that providing chitosan and hinokitiol in an anti-microbial amount also inherently has at least some degree of antifungal activity. Note that the claims are silent as to any degree of antibacterial or anti-fungal activity, and thus are readable on the most minimal degree of activity" (Page

2, Paper No. 8).

In response to the Examiner's suggestion, Applicant has written new Claim 21 to replace original Claims 1 and 2. Claim 21 recites that the composition has protectant and/or eradicant activity and substantially inhibits bacterial and fungal growth.

The rejection is overcome since it is believed that the claims patentably distinguish from Atsumi *et al.*

In view of the above remarks, it is respectfully requested that the rejection of Claims 1, 2, 4, 5, 10-13 and 16-20 under 35 U.S.C. 102 (a), be withdrawn.

Rejection of Claims* 3, 6-9, 14 and 15 *under 35 U.S.C.103(a)

9. The Examiner has rejected Claims 3, 6-9, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Atsumi *et al.* (JP 200217509) in view of Takahashi (U.S. Patent 6,352,727, 2002) for the reasons given in the Office Action of December 4, 2002, Paper No. 6.

The Examiner alleges that as evidenced by Takahashi, it is known to add various additives to an antibacterial composition for its particular functionality such as the recited antioxidants and stabilizers and surfactants and to add such ingredients to the composition of Atsumi *et al.* for their art recognized and applicants' intended function would have been obvious. The Examiner continues, "Takahashi teaches the many varieties of vehicles that the art conventionally uses to introduce the anti-bacterial composition" such as wipes, spray dispenser, and packaging material. "To therefore modify Atsumi and provide the antibacterial composition in conventional vehicles would

have been obvious" (Paper No. 6, Paragraphs bridging Pages 2 and 3).

Applicant respectfully disagrees with the Examiner's assertion that a *prima facie* case of obviousness has been established. It is stated in the MPEP (MPEP 706.02(j) that "[T]o establish a *prima facie* case of obviousness three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references to combine reference teachings. Second, there must be reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure."

"The prior art reference (or references when combined) must teach or suggest all the claim limitations." The references cited by the Examiner do not teach or suggest all claim limitations. There is nothing in Takahashi which overcomes the deficiencies of the Atsumi *et al.* reference as discussed *supra*.

Takahashi does not claim "chitosan *salts*". The instant specification discloses chitosan salts, chitosan-sorbate, chitosan-acetate, and chitosan-propionate, for example, in Example 2, Table 2; Example 3, Tables 4, 5, and 7; Example 4, Table 9; Example 5, Table 10. The claims recite "chitosan salts". Takahashi claims chitosan. Takahashi discloses that "chitosan derivatives of which aqueous solubility is increased, such as chitosan oligosaccharide, chitosan lactate, chitosan chloride or the like can also be used. However, in order to prepare a bactericide (or a fungicide) having a strong bactericidal (or a fungicidal) activity, chitosan is preferably used " (Column 5, Lines 44-

49). Thus, Takahashi does not particularly point to the salts of the invention, and in fact, teaches that chitosan is preferable. The characteristics of the chitosan salts of the invention thus are different than the characteristics of chitosan of Takahashi according to Takahashi.

Thus, the prior art reference (or references when combined) do not teach or suggest all the claim limitations.

10. Further, Applicant respectfully traverses the Examiner's allegation that to therefore modify Atsumi and provide the antibacterial composition in conventional vehicles would have been obvious". There is a lack of a teaching of the motivation to combine the references.

11. Therefore, taking the following facts into account: (1) the absence in Atsumi *et al.* of a teaching of chitosan salts and synergistic results with comparable concentrations of essential oils and chitosan salts (and the absence in Takahashi of a teaching of chitosan salts and synergistic results with comparable concentrations of essential oils and chitosan salts) (2) the lack of a teaching of the motivation to combine the references and (3) the absence of a reasonable expectation of success to obtain particular synergistic combinations and concentrations, it would not have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have obtained the claimed invention.

In view of the above, it is respectfully requested that the rejection of 3, 6-9, 14 and 15 under 35 U.S.C. paragraph 103 be withdrawn.

CONCLUSION

The final office action was mailed on August 26, 2003, and this response is submitted within the three month period for reply, therefore no extension of time is required and no fee is due. Please charge any additional fees which may be required at any time during prosecution of the instant application to deposit account 50-2134.

In view of the above amendments and remarks, it is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

November 26, 2003 Evelyn M. Rabin

Date

Evelyn M. Rabin, Ph.D., Patent Advisor
Registration No. 44,480
USDA-ARS-OTT
5601 Sunnyside Ave., Rm. 4-1186
Beltsville, Maryland 20705-5131
Telephone: (301) 504-4781
Fax: (301) 504-5060

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,

on November 26, 2003 .

(Date)

Evelyn M. Rabin

(Name of applicant, assignee, or Registered Representative)

Evelyn M. Rabin — November 26, 2003

(Signature) (Date)